Assessment of the glycemic responses to nutritional products

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22371

Source
Nationaal Trial Register

Brief title
Glow

Health condition

Not applicable

Sponsors and support

Primary sponsor: Danone Nutricia Research
Source(s) of monetary or material Support: Danone Nutricia Research

Intervention

Outcome measures

Primary outcome

The primary outcome is the glycemic index of the test products

Secondary outcome

The secondary outcome parameters in this study are:

- GL=GI*available carbohydrate/given amount
Capillary blood glucose mmol/l and iAUC0-120 [mmol/l*min] of the reference product and test product(s)
- Capillary blood glucose iCmax [mmol/l] and Tmax [min] of the reference product and test product(s)
- Appetite profile and liking of the test product using visual analogue scales (VAS, mm)

Study description

Background summary

This is a generic protocol for the assessment of glycemic responses to nutritional products. During a study visit fasted subjects will consume one serving of the reference product or (one of) the test product(s). Capillary blood samples will be taken at baseline and at several time-points over a 2-hr period. Appetite and liking will be assessed by completing a VAS scale on several time-points. Several nutritional products will be tested over time.

Study objective

Not applicable

Study design

Time points of the outcome; for example: V0 (screening); V1; V2 (≥48 hrs), V# (≥48 hrs)

Intervention

Duration of intervention: depending on number of test products

Intervention group:
- Test product(s):
All test products contain 25 or 50 g of available carbohydrates.
- Reference product (one to be chosen):
a) anhydrous glucose powder (25 or 50 g)
b) dextrose (glucose monohydrate, 27,5 or 55 g)
c) commercial solution containing glucose (25 or 50 g)

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥ 18 and ≤ 60 years
2. Body Mass Index (BMI) ≥ 18.5 and ≤ 24.9 kg/m2
3. Written informed consent
4. Willingness and ability to comply with the protocol
5. Judged by the investigator to be in good health

Exclusion criteria

1. Known Diabetes Mellitus type I or type II, rebound hypoglycaemia and/or any other medical condition that interferes with glucose
2. Any use of anticoagulants, steroids, protease inhibitors or antipsychotics and/or any medication known to affect glucose tolerance and/or to influence digestion and absorption of nutrients within 1 week of screening, in opinion of the investigator
3. Any known disease which influence digestion and absorption of nutrients within 1 week of screening
4. Any known relevant food allergy or intolerance
5. Adherence to a strict vegan diet and/or a weight loss program
6. Any known bleeding disorder

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-11-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
not applicable

Ethics review

Positive opinion

Date:	12-11-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49247
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8151
CCMO	NL71190.056.19
OMON	NL-OMON49247

Study results

Summary results
not applicable